K110403

SILMET

SEP - 8 2011

5. 510(k) Summary

This summary of 510(k) safety and effectiveness is being submitted in accordance with requirements of 21 C.F.R. part 872.3690

Date prepared: February 8, 2011

Company

Name	Silmet Ltd
Address	12 Hassadna St., Industrial Park Or Yehuda 60200. Israel
Telephone	972 3 5331474
Fax	972 3 5331581
Contact	Moshe Zalsman
e-mail	moshe@silmet.co.il

Devices

Trade Name:	**ProLink adhesives** (ProLink, ProLink SE)
Classification Name:	Resin Tooth Bonding Agent (21 CFR 872.3200)
Common Name:	Dental Adhesives
Regulatory class:	Class II

Predicate Devices

Adper Single Bond Plus	(K962785, 3M Dental Products)
iBond Total Etch	(K083652, Heraeus Kulzer, GmbH)
G-Bond	(K041471, GC America)
Clearfil Tri-S Bond	(K042913, Kuraray Medical Inc.)

Description

- ProLink is a 5th generation dentin/enamel single step bonding agent. The primer and adhesive are combined into a single component for ease of application. ProLink delivers outstanding shear bonding values to dentin, enamel & all popular light, dual or auto-cure composites.

- ProLink SE is a 7th generation light cured self etching dentin/enamel bonding agent. The etch, primer and adhesive are combined into a single component for ease of application. Separate conditioning (etching) of the enamel and dentine is not required.

K110403

SILMET

Device function, scientific concept, physical and performance characteristics

ProLink adhesives establish a bond to both the filling material and the dental hard tissue, i.e. enamel and dentin.
There has been dramatic progression in the adhesion of dental adhesives and resins to enamel and dentin in the 40 years since Buonocore[1] introduced the technique of etching enamel with phosphoric acid to improve adhesion to enamel.

Device components and technological characteristic

Similar to all other dental adhesives ProLink adhesives typically contain resin monomers, curing initiators, inhibitors or stabilizers, solvents and inorganic filler. The resin matrix functions as a backbone providing structural continuity and thus physical – mechanical properties such as strength.

Table 1. Device Composition

Components			Function
Fillers			
Fumed silica			Filler particles modify the viscosity of the adhesive, offer higher elasticity
	ProLink	ProLink SE	
Weight of filler:	5.5 %	3 %	
Size of filler:	6 microns	0.4 microns	
Resin components			
Triethyleneglycol dimethacrylate (TEDGMA) Urethandimethacrylate (UDMA)			Cross linkers that directly provide mechanical strength to adhesive system by forming densely cross linked polymers, helps prevent substantial water uptake after curing
2-Hydroxyethylmethacrylate (HEMA)			Its hydrophilicity makes it an excellent adhesion promoting monomer
Multifunctional dimethacrylates			enhance wetting of dentin and thus improves bond strength
Camphoroquinone Ethyl 4-dimethylaminobenzoate			Photo initiators: set off radical polymerization reaction of monomer
Ethanol & Acetone			Solvents: promote good penetration of monomers in the collagen network of the demineralized dentin

[1] Buonocore MG. A simple method of increasing the adhesion of acrylic filling materials to enamel surfaces. J Dent Res. 1955;34:849–853.

SILMET LTD. 12 Hassadna St. Industrial Park. Or Yehuda 60200 Israel Tel: +972 3 5331474 Fax. +972 3 5331581 e-mail:info@silmetdental.com www.silmetdental.com

K110403

Indications for use

ProLink	ProLink SE
Direct Composite or Compomer restorations	Bonding of composites to tooth structure
Adhesive cementation	Core Build up
Composite repair	Adhesive cementation of crown & bridges, including inlays and onlays

Contraindications

Patients with a history of hypersensitivity to methacrylate monomers.
Pulp capping

Performance characteristics

In addition to withstanding mechanical forces, and in particular shrinkage stress, the ProLink adhesives feature the following characteristics.

- high bond strength
- a thin film thickness to ensure easy and complete seating of restorations
- shelf stability
- post placement stability.

SILMET LTD. 12 Hassadna St. Industrial Park, Or Yehuda 60200 Israel. Tel: + 972 3 5331474 Fax: +972 3 5331581 e-mail:info@silmetdental.com www.silmetdental.com

Summary of Physical Tests.

This 510(k) submission includes data from bench testing to evaluate the performance of the ProLink adhesives (ProLink, ProLink SE) compared to the following predicate devices:

Adper Single Bond Plus	(K962785)
iBond Total Etch	(K083652)
G-Bond	(K041471)
Clearfil Tri-S Bond	(K042913)

Properties evaluated include:

1. Shear Bond strength to etched enamel and to etched dentin
2. Marginal integrity

Substantial Equivalence Discussion

The information provided in this 510(k) submission shows that the ProLink adhesives are substantially equivalent to:

Adper Single Bond Plus	(K962785, 3M Dental Products)
iBond Total Etch	(K083652, Heraeus Kulzer, GmbH)
G-Bond	(K041471, GC America)
Clearfil Tri-S Bond	(K042913, Kuraray Medical Inc.)

The equivalence is in terms of intended use, indications for use, composition, physical properties and technological characteristics. A comparison of technological characteristics is provided below.

Table 2: Similarity of Technological properties to predicate devices

Technological property	**ProLink Adhesives**	**Adper Single Bond Plus**	**iBond Total Etch**	**G-Bond**	**Clearfil Tri-S Bond**
Camphorquinone/amine photoinitiator system	X	X	X	X	X
Methacrylate-based resin matrix	X	X	X	X	X
Silane treated fillers	X	X	X	X	X
Forms essential hybrid zone	X	X	X	X	X
High Hydrophilicity	X	X	X	X	X

The prior use of all the components in the legally marketed predicate devices supports our decision that additional testing for bio-compatibility with the final formulation are not necessary.
We believe that the prior use of these components in legally marketed devices and the performance data and results support the safety and effectiveness of **ProLink adhesives** for the intended use.

Conclusion

In accordance with 21 C.F.R. part 807 and FDA's Guidance for the preparation of Premarket Notifications for Dental Composites" and based on the information provided in this premarket notification, Silmet Ltd. concludes that **ProLink Adhesives** are safe and effective and substantially equivalent to the predicate devices described herein.

SILMET LTD. 8 February 2011 CEO: Moshe Zalsman Signature: 

SILMET LTD. 12 Hassadna St. Industrial Park, Or Yehuda 60200 Israel Tel: +972 3 5331474 Fax: +972 3 5331581 e-mail:info@silmetdental.com www.silmetdental.com

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room –WO66-G609
Silver Spring, MD 20993-0002

Mr. Moshe Zalsman
CEO
Silmet Limited
12 Hassadna Street
Or Yehuda
Isreal 60200

SEP - 8 2011

Re: K110403
Trade/Device Name: ProLink Adhesive (ProLink, ProLink SE)
Regulation Number: 21 CFR 872.3200
Regulation Name: Resin Tooth Bonding Agent
Regulatory Class: II
Product Code: KLE
Dated: September 4, 2011
Received: September 7, 2011

Dear Mr. Zalsman:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

for

Anthony D. Watson, B.S., M.S., M.B.A.
Director
Division of Anesthesiology, General Hospital,
Infection Control and Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

4. Indications for Use Statement

510(k) Number (if known): _____ K110403

Device Name: ProLink adhesives (ProLink, ProLink SE)

Products	Indications for Use
ProLink	Direct Composite or Compomer restorations Adhesive cementation Composite repair
ProLink SE	Bonding of composites to tooth structure Core Build up Adhesive cementation of crown & bridges, including inlays and onlays

Prescription Use __√__ (Part 21 CFR 801 Subpart D)

AND/OR

Over-The-Counter Use _____ (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE OF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Page __ of ___

Susan Runner

(Division Sign-Off)
Division of Anesthesiology, General Hospital
Infection Control, Dental Devices

510(k) Number: K110403

SILMET LTD. 12 Hassadna St. Industrial Park, Or Yehuda 60200 Israel. Tel +972 3 5331474 Fax: +972 3 5331581 e-mail:info@silmetdental.com www.silmetdental.com